

Art Unit: 1744

- 7 -

Serial No.: 09/707,852
 Conf. No.: 9828

REMARKS

Regarding the Office Action mailed February 11, 2005, Applicants have corrected the Response filed February 3, 2005 in the instant response.

As requested by the Examiner, the Applicants have amended "Membranes 30" to "Membranes 34" on page 11, line 10. This appears to have been an inadvertent typographical error.

Claim 156 has been amended to recite an oxygen permeable thin layer interface, where distribution of the oxygen to the cells takes place through the thin layer interface, and where the thin layer interface provides the ability for cell nutrient transfer to take place. Support for this amendment can be found in the specification, for example, on page 5, lines 26-29. The "gas enclosure" clause in claim 156 has also been deleted. Additionally, claim 156 has been amended to recite a protein. Support for this amendment can also be found in the specification, for example, on page 10, lines 17-19.

New claims 174 and 175 have been added. Claim 174 recites a system for maintaining and cultivating cells, including membrane defining at least one wall of a fluid pathway, across which product passes. Claim 175 is somewhat similar to claim 156 but, as a method claim, recites operating a plurality of reaction units in parallel, introducing nutrients into the chamber via an inlet, introducing oxygen into the chamber across a thin layer interface, cultivating the cells in culture, and releasing a protein resulting from the interaction involving the cells in the chamber. Support for these claims can be found throughout the specification, for example, on page 7, lines 6-19; page 10, lines 2-22; page 11, lines 9-14; page 12, lines 16-20, or Fig. 1.

Claims 156-175 are now pending for examination.

Rejections under 35 U.S.C. §112, ¶1

Claims 156-173 have been rejected under 35 U.S.C. §112, ¶1, as failing to comply with the written description requirement. The Office Action states that the specification does not support a chamber having a surface suitable for cell growth, a membrane defining at least one wall of the chamber where the membrane is able to transport oxygen, or a gas enclosure positioned proximate the chamber for facilitating oxygen transfer across the membrane.

With respect to the recitation of a chamber having a surface suitable for cell growth, Applicants note that page 10, lines 15-19 describe a reaction unit, used for cell cultivation, in

Art Unit: 1744

- 8 -

Serial No.: 09/707,852
 Conf. No.: 9828

which cell cultivation is promoted by the introduction, to the cells, of cell feed, and proper pH, O₂ concentration, and temperature for cell cultivation. O₂ concentration can be controlled by introducing oxygen across a thin-layer interface to a cell cultivation chamber (page 5, lines 25-29). Cells can be immobilized on a surface of the chamber by, e.g., surface functionalization and subsequent reaction or entrapment within a host membrane (page 10, lines 17-19). Thus, the specification is able to support a chamber having a surface suitable for cell growth.

With respect to the recitation of a membrane defining at least one wall of the chamber where the membrane is able to transport oxygen, claim 156 has been amended to recite a "thin layer interface" instead of a membrane, and the application on page 5, lines 25-29 states that "With enhanced oxygen and nutrient distribution, a microreactor of the invention demonstrates increased performance in terms of cell viability. The microreactor geometry resembles closely the natural environment of cells whereby diffusional oxygen and nutrient transfer take place through a high surface area, thin layer interface." As this passage describes, the interface separates the chamber containing the cells with a portion of the reactor or other environment containing oxygen or nutrients that can diffuse through the interface to the cells, and thus, the interface defines a wall of the chamber containing the cells.

Other points raised in the Office Action have been rendered moot by the above amendments.

Thus, it is believed that the specification supports the claims rejected on this ground, as amended, and it is therefore respectfully requested that the rejection of claims 156-173 under 35 U.S.C. §112, ¶1 be withdrawn.

Rejections under 35 U.S.C. §112, ¶2

Claims 156-173 have been rejected under 35 U.S.C. §112, ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states that the "chamber being constructed and arranged to maintain and cultivate cells in culture for at least a period of time sufficient to generate | a product resulting from the interaction of the cells with oxygen and/or nutrients and/or other components" is indefinite.

At the outset, it should be noted that an element in a claim that is described as being "constructed and arranged" is not *per se* indefinite. Thus, claim 156 includes systems that

Art Unit: 1744

- 9 -

Serial No.: 09/707,852
Conf. No.: 9828

include reactors that allow for the maintenance and cultivation of cells in culture for periods of time sufficient to generate product, and this would be readily ascertainable by those of ordinary skill in the art. Examples of such chambers are described in the specification. Moreover, the requirement of 35 U.S.C. §112, ¶2 is that those of ordinary skill in the art, upon reading the claim, will understand the meaning of the claim, that is, the claim's metes and bounds. This requirement is satisfied by the language challenged in the Office Action.

Thus, it is believed that independent claim 156 and dependent claims 157-173, which depend, directly or indirectly, from claim 156, are not indefinite, and it is therefore respectfully requested that the rejection of these claims be withdrawn.

Objection to the Specification

The specification has been objected to by the Patent Office, as "Membranes 30" on page 11, line 10 should be "Membranes 34."

Applicants have amended the specification accordingly. Thus, it is respectfully requested that the objection be withdrawn.

Objection to the Amendment

The Amendment filed on August 6, 2004 has also been objected under 35 U.S.C. §132, as the Patent Office claims that it introduces new matter into the disclosure.

While, for the reasons discussed above with respect to the objections under 35 U.S.C. §112, it is believed that this rejection is improper, it is believed that the amendments presented herein render the objection on this ground moot. Thus, it is respectfully requested that this objection be withdrawn.

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, that the application is not in condition for allowance, then the Examiner is requested to call the undersigned at the telephone number listed below.

Serial No.: 09/707,852
Conf. No.: 9828

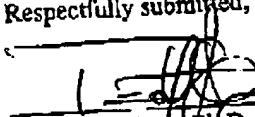
- 10 -

Art Unit: 1744

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By:


Timothy J. Oyer, Ph.D., Reg. No. 36,628
Tani Chen, Sc.D./Reg. No. 52,728
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: B1102.7000011500
Date: February 24, 2005
x02/28/05x